

battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

**§ 886.5916 Rigid gas permeable contact lens.**

(a) *Identification.* A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

**§ 886.5918 Rigid gas permeable contact lens care products.**

(a) *Identification.* A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/re-wetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

[62 FR 30987, June 6, 1997]

**§ 886.5925 Soft (hydrophilic) contact lens.**

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

**§ 886.5928 Soft (hydrophilic) contact lens care products.**

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/re-wetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

[62 FR 30988, June 6, 1997]

**§ 886.5933 [Reserved]**

## PART 888—ORTHOPEDIC DEVICES

### Subpart A—General Provisions

Sec.

888.1 Scope.

888.3 Effective dates of requirement for premarket approval.

888.5 Resurfacing technique.

888.6 Degree of constraint.

888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).